Medical Device Reporting (MDR) for Hospitals Who Reprocess and Reuse Single Use Devices

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Legal Authority

- Statutory requirements for Device User Facilities and Manufacturers
  - 519 (a), (b) and (c) of Food Drug & Cosmetic (FD&C) Act
- Regulatory requirements for Medical Device Reporting (MDR)
  - 21 Code of Federal Regulations (CFR), Part 803

New Enforcement Issues

- Guidance document, *Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals*, issued August 14, 2000
  - Hospitals must comply with pre-market and post-market regulations as device manufacturers.

How can a Hospital be a Device Manufacturer?

- A manufacturer is:
  - any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures.
- Therefore:
  - a hospital that reprocesses SUDs is a manufacturer.

Manufacturer (Hospital) Reporting Requirements Begin August 14, 2002

- Hospital SUD Reprocessors must then submit:
  - death, serious injury and malfunction adverse event reports to FDA within 30 calendar days (803.30 and 803.50)
  - supplemental reports within 30 calendar days of receipt of new information (803.56)
  - 5-day reports within 5 work days (803.53)
  - Initial Baseline, Annual Update reports (FDA Form 3417) (803.55)

Hospitals Have a Dual Reporting Role

- Hospitals as device user facilities must comply
  - Parts 803.18, 803.30, 803.32, and 803.33
- Hospitals as manufacturers (SUD reprocessors) must comply
  - Parts 803.18, 803.50, 803.52, 803.53, 803.55, 803.56

Hospitals that use third-party reprocessed SUDs still must report events as user facilities.

How Do I Report?

If event involves SUD not reprocessed by hospital:

- Complete 3500A as a device user facility (A-F) and send report within 10 workdays to:
  - manufacturer and FDA if death
  - manufacturer (or FDA if manufacturer is unknown) if serious injury

If the SUD is reprocessed by a third-party reprocessor, it is the manufacturer.

How Do I Report?

If event involves SUD reprocessed by the hospital,

- as the device user facility,
  - fill out 3500A (A-F)
  - send 3500A to FDA and/or the manufacturer within 10 workdays

How Do I Report?

- as the manufacturer,
  - conduct investigation of event (803.50 and 820.198)
  - fill out 3500A (G-H)
  - complete baseline report form 3417
  - send 3500A and 3417 to FDA within 5 workdays (remedial action) or 30 calendar days

What About Death Reports?

- Device user facilities must:
  - submit death reports to FDA and manufacturer within 10 work days.
- Hospital as SUD reprocessor must:
  - submit death reports within 30 calendar days.

To avoid duplicate submissions of 3500A, hospital may submit death report (A-F and G-H) within 10 work days

Written MDR Procedures & Files (21 CFR Part 803.18)

- User facilities & manufacturers are required to:
  - develop and implement written MDR procedures
  - establish and maintain MDR event files containing all documentation related to event and decision making process

Hospital SUD reprocessor must incorporate additional requirements under 803.18(e).

Where Can I Find More Information?

- *Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use* (April 24, 2001) (Q & A document)

http://www.fda.gov/cdrh/osb/guidance/1334.html

http://www.fda.gov/cdrh/reuse/index.shtml

Need More Information?

- Inquiries may be directed to:

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